EXHIBIT B

INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
VALLEY CREST NURSING HOME

I. PREAMBLE

Valley Crest Nursing Home ("Valley Crest"), a skilled nursing facility owned and operated by the County of Luzerne in the Commonwealth of Pennsylvania, enters into this Integrity Agreement ("Agreement") with the Office of Inspector General ("OIG") of the United States Department of Health and Human Services ("HHS") to promote compliance by its employees, contractors, agents, third parties engaged to bill or submit reimbursement claims, and all other individuals responsible for the provision, marketing or documentation of items or services reimbursable by Federal health care programs, or in the preparation of claims, reports or other requests for reimbursement for such items or services ("Covered Persons") with the requirements of the Medicare, Medicaid and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) ("Federal health care program requirements"). Valley Crest's compliance with the terms and conditions in this Agreement shall constitute an element of Valley Crest's present responsibility with regard to participation in the Federal health care programs. Contemporaneously with this Agreement, Valley Crest is entering into a Settlement Agreement with the United States, and this Agreement is incorporated by reference into the Settlement Agreement.

Prior to the execution of this Agreement, Valley Crest voluntarily established a compliance plan known as the Compliance Program ("Program"). That Program provides for policies and procedures and, as represented by Valley Crest in this Agreement, is aimed at ensuring that its participation in the Federal health care programs (which includes any requests for payments) is in conformity with the statutes, regulations and other directives applicable to the Federal health care programs. Therefore, pursuant to this Agreement, Valley Crest hereby agrees to maintain in full operation the Program as it relates to participation in the Federal health care programs for the term of this Agreement. The Program may be modified by Valley Crest as appropriate, but, at a minimum, shall comply with the integrity obligations set forth in this Agreement.

II. TERM OF THE AGREEMENT

The period of the compliance obligations assumed by Valley Crest under this Agreement shall be five (5) years from the effective date of this Agreement (unless otherwise specified).

The effective date of this Agreement will be the date on which the final signatory of this Agreement executes this Agreement (the "effective date").

Sections VII, VIII, IX, X and XI shall remain in effect until OIG has completed its review of the final annual report and any additional materials submitted by Valley Crest pursuant to OIG's request. Sections VII, VIII, IX, X and XI shall expire no later than 120 days from OIG's receipt of (1) Valley Crest's final annual report or (2) any additional materials submitted by Valley Crest pursuant to OIG's request, whichever is later.

III. <u>Integrity Obligations</u>

Valley Crest shall maintain its compliance program which shall include, at a minimum, the following elements.

A. Compliance Officer and Committee. Valley Crest represents that it has appointed an individual to serve as its Compliance Officer ("Compliance Officer"), who shall be responsible for developing and implementing policies, procedures, and practices designed to ensure compliance with the requirements set forth in this Agreement and with the requirements of the Federal health care programs. The Compliance Officer shall be a member of senior management of Valley Crest, shall make regular (at least quarterly) reports regarding compliance matters directly to Valley Crest's Administrator, Advisory Board, its Chief Financial Officer and/or the Luzerne County Commissioners, and shall be authorized to report to these individuals or entities at any time. The Compliance Officer shall be responsible for monitoring the day-to-day activities engaged in by Valley Crest to further its compliance objectives as well as any reporting obligations created under this Agreement. In the event a new Compliance Officer is appointed during the term of this Agreement, Valley Crest shall notify OIG, in writing, within fifteen (15) days of such a change.

Valley Crest represents that it has appointed a Compliance Committee (also known as the Advisory Board). The Compliance Committee shall, at a minimum, include the Compliance Officer and any other appropriate individuals as necessary to meet the requirements of this Agreement within Valley Crest's business structure (e.g., senior executives of each major department, such as billing, clinical, human resources, audit, and operations). The Compliance Officer shall chair the Compliance Committee and the Committee shall support the Compliance Officer in fulfilling his/her responsibilities.

Any changes in the composition of the Compliance Committee, or any actions or changes that would affect the Compliance Committee's ability to perform the duties necessary to meet the obligations in this Agreement, must be reported to OIG, in writing, within fifteen (15) days of such a change.

B. Written Standards.

1. <u>Code of Conduct</u>. Valley Crest represents that it has established a Code of Conduct. The Code of Conduct shall be distributed to all Covered Persons and agents as a part

of its Program's educational implementation. Valley Crest shall continue to make the promotion of, and adherence to, the Code of Conduct an element in evaluating the performance of Covered Persons. The Code of Conduct shall, at a minimum, set forth:

- a. Valley Crest's commitment to full compliance with all statutes, regulations, and guidelines applicable to Federal health care programs, including its commitment to prepare and submit accurate billings and reports consistent with Federal health care program regulations and procedures or instructions otherwise communicated by the Health Care Financing Administration ("HCFA"), and/or its agents;
- b. Valley Crest's requirement that all Covered Persons shall be expected to comply with all statutes, regulations, and guidelines applicable to Federal health care programs and with Valley Crest's own Policies and Procedures (including the requirements of this Agreement);
- c. The requirement that all Covered Persons shall be expected to report suspected violations of any statute, regulation, or guideline applicable to Federal health care programs or suspected violations of Valley Crest's own Policies and Procedures;
- d. The possible consequences to both Valley Crest and to any Covered Person of failure to comply with all statutes, regulations, and guidelines applicable to Federal health care programs and with Valley Crest's own Policies and Procedures or of failure to report such non-compliance; and
- e. The right of all Covered Persons to use the confidential disclosure program, as well as Valley Crest's commitment to confidentiality and non-retaliation with respect to disclosures.

To the extent not already accomplished, within one hundred and eighty (180) days of the effective date of the Agreement and as part of the educational implementation of Valley Crest's Program, each Covered Person shall certify, in writing, that he or she has received, read, understood, and will abide by Valley Crest's Code of Conduct. New Covered Persons shall receive the Code of Conduct and shall complete the required certification within thirty (30) days after becoming a Covered Person or within one hundred and eighty (180) days of the effective date of the Agreement, whichever is later.

Valley Crest shall annually review the Code of Conduct and shall make any necessary revisions. These revisions shall be distributed within thirty (30) days of initiating such a change. Covered Persons shall certify that they have received, read, understood and will abide by the revised Code of Conduct within thirty (30) days of the finalization of such revisions.

2. <u>Policies and Procedures</u>. To the extent not already accomplished, within ninety (90) days of the effective date of this Agreement, Valley Crest shall develop and initiate

the implementation of written Policies and Procedures regarding the operation of its Compliance Program and regarding its compliance with all Federal and state health care statutes, regulations, and guidelines. At a minimum, the Policies and Procedures shall specifically address:

- a. Measures designed to ensure that Valley Crest fully complies with the particular provisions of Titles XVIII and XIX of the Social Security Act, 42 U.S.C. §§ 1395-1395ggg and 1396-1396v, and all regulations and guidelines promulgated pursuant to these statutes, including, but not limited to, 42 C.F.R. Parts 424 and 483;
- b. Measures designed to ensure that Valley Crest complies with all requirements applicable to Medicare's Prospective Payment System (PPS) for skilled nursing facilities, including but not limited to: ensuring the accuracy of the clinical data required under the Minimum Data Set ("MDS"); ensuring that facilities are appropriately and accurately using the current Resource Utilization Groups ("RUG") classification system; ensuring the accuracy of billing and cost report preparation policies and procedures;
- c. Measures designed to ensure that Valley Crest appropriately screens all independent contractors with which it contracts, specifically ensuring that all individuals employed by such independent contractors are appropriately licensed and qualified;
- d. Methods for employees to make disclosures or otherwise report on compliance issues to Valley Crest management through the Confidential Disclosure Program required by Section III.E; and
- e. Disciplinary policies designed to ensure that individuals whose conduct has contributed to a violation of Valley Crest's Program or of Federal health care program requirements are retrained, and/or disciplined, and/or terminated, as appropriate.

To the extent not already accomplished, within ninety (90) days of the effective date of this Agreement, the relevant portions of the Policies and Procedures shall be distributed to all individuals whose job functions are related to those Policies and Procedures. Appropriate and knowledgeable staff should be available to explain the Policies and Procedures.

Valley Crest shall assess and update the Policies and Procedures at least annually and more frequently, as necessary and appropriate. Within thirty (30) days of the effective date of any revisions, the relevant portions of any such revised Policies and Procedures shall be distributed to all individuals whose job functions are related to those Policies and Procedures. The Policies and Procedures will be available to OIG, upon request.

C. <u>Training and Education</u>. Valley Crest shall meet the following training requirements. These training requirements are cumulative (not exclusive), so that one person may be required

to attend training in several substantive areas in addition to the general training. Persons providing the training must be knowledgeable about the relevant subject area. All training requirements set forth below shall be implemented within ninety (90) days of the effective date of this Agreement and thereafter repeated annually during the term of the Agreement.

- 1. <u>General Training</u>. Valley Crest shall provide at least one (1) hour of training to each Covered Person. This general training shall explain Valley Crest's:
 - a. Integrity Agreement requirements; and
 - b. Compliance Program (including the Code of Conduct and the Policies and Procedures as they pertain to general compliance issues).

All training materials shall be made available to OIG, upon request.

2. Specific Training.

- a. Each Covered Person who is involved directly or indirectly in the delivery of patient care shall receive at least four (4) hours of training in addition to the general training required above. This training shall include a discussion of:
 - i. The personal obligation of each individual involved in patient care to ensure that the information provided pertaining to such care is accurate;
 - ii. Applicable statutes, regulations, and program requirements and directives relevant to the person's duties;
 - iii. The legal sanctions for improper submissions to Federal health care programs; and
 - iv. Examples of proper and improper practices related to Federal health care programs.
- b. Each Covered Person who is involved directly or indirectly in the preparation or submission of information (including claims, bills, and reports) to any Federal health care program shall receive at least six (6) hours of training in addition to the general training required above. This training shall include a discussion of:
 - i. The submission of accurate information (e.g., MDS) to Federal health care programs;

- ii. Policies, procedures and other requirements applicable to the documentation of medical records;
- iii. Policies and procedures related to proper billing for services to Federal health care programs and claims for payments through submission of Federal health care program cost reporting and information forms;
- iv. The personal obligation of each individual involved in the billing process, documentation, and/or the reimbursement process to ensure that the information provided is accurate;
- v. Applicable statutes, regulations, and program requirements and directives relevant to the person's duties;
- vi. The legal sanctions for improper submissions to Federal health care programs; and
- vii. Examples of proper and improper practices related to Federal health care programs.
- 3. New Covered Persons. Affected new Covered Persons shall receive the training required by this Agreement within thirty (30) days of the beginning of their employment or contractual relationship with Valley Crest or within ninety (90) days of the effective date of this Agreement, whichever is later. New Covered Persons involved directly in the delivery of patient care or in the preparation or submission of information (including claims, bills, and reports) to any Federal health care program shall be supervised by trained Covered Persons until they have completed the specific training relevant to their delivery of patient care and/or their preparation or submission of information to Federal health care programs.
- 4. <u>Certifications and Retention</u>. Each person who is required to attend training shall certify, in writing, that he or she has attended the required training. The certification shall specify the type of training received and the date received. The Compliance Officer (or his or her designee) shall retain the certifications as well as the specific course materials and make all of these certifications and materials available to OIG, upon request. For the purposes of meeting the obligations under this Section III.C, for the term of the first Annual Report under this Agreement, OIG shall credit Valley Crest's training and education activities carried out pursuant to the Program since September 1, 2000 to the extent such training satisfies the requirements set forth above.

D. Review Procedures.

1. General Description.

- a. Retention of Independent Review Organization. Within ninety (90) days of the effective date of this Agreement, Valley Crest shall retain an entity (or entities), such as an accounting, auditing or consulting firm (hereinafter "Independent Review Organization" or "IRO"), to perform review engagements to assist Valley Crest in evaluating its billing and coding practices and its compliance obligations pursuant to this Agreement. Each Independent Review Organization retained by Valley Crest shall have expertise in the billing, coding, reporting and other requirements of the Federal health care program(s) from which Valley Crest seeks reimbursement.
- b. Types of Engagements. The Independent Review Organization(s) shall conduct two (2) separate engagements. One engagement shall address Valley Crest's billing and coding to the Federal health care programs ("Billing Engagement"). The second engagement shall address Valley Crest's compliance with the obligations assumed under this Agreement ("Compliance Engagement").
- c. Frequency of Billing and Compliance Engagements. The Billing Engagement shall be performed annually and shall cover each of the one-year periods beginning with the effective date of this Agreement. The IRO(s) shall perform all components of each annual Billing Engagement. The Compliance Engagement shall be performed by the IRO for the first one-year period beginning with the effective date of this Agreement.
- d. Retention of Records. The IRO and Valley Crest shall retain and make available to OIG upon request all work papers, supporting documentation, correspondence, and draft reports related to the engagements.
- 2. <u>Billing Engagement</u>. The Billing Engagement shall be composed of two (2) separate reviews, a "Claims Review" and a "Systems Review." The Claims Review and corresponding Claims Review Report are discussed in detail in Appendix A to this Agreement, which is incorporated by reference.
 - a. Claims Review. The IRO shall perform a Claims Review to identify any overpayments through an appraisal of Paid Claims submitted by Valley Crest to the Medicare and Medicaid programs. The Claims Review shall be performed in accordance with the procedures set forth in Appendix A to this Agreement.

- b. Claims Review Report. The IRO shall prepare a report based upon each Claims Review performed ("Claims Review Report"). The Claims Review Report shall be created in accordance with the procedures set forth in Appendix A to this Agreement.
- c. Systems Review. The IRO shall review Valley Crest's billing and coding systems and/or operations and cost report preparation process (the "Systems Review"). The Systems Review shall consist of a thorough review of the following:
 - i. Valley Crest's documentation (<u>e.g.</u>, cost reports and cost statements), billing, reporting (<u>e.g.</u>, reporting of MDS and other information relevant to RUG) and operations (including, but not limited to, the operation of the billing system, safeguards to ensure proper claim submission and billing, internal controls, procedures to correct inaccurate billing, and effectiveness of the system);
 - ii. Valley Crest's coding systems and/or operations relating to claims submitted to all Federal health care programs (including, but not limited to, the process by which claims are coded, safeguards to ensure proper coding, and procedures to correct inaccurate coding); and
 - iii. Valley Crest's cost report, cost statement, information statement and payment request preparation process relating to any and all costs submitted to Federal health care programs (including, but not limited to, the steps Valley Crest takes to ensure that the proper information is being recorded on submissions to Federal health care programs and safeguards to ensure that only proper costs and dollar amounts are being submitted for reimbursement to such programs).
- d. Systems Review Report. The IRO shall prepare a report based upon each Systems Review performed ("Systems Review Report"). The Systems Review Report shall include the IRO's findings and supporting rationale regarding:
 - i. the strengths and weaknesses in Valley Crest's billing systems and/or operations;
 - ii. the strengths and weaknesses in Valley Crest's coding systems and/or operations;
 - iii. the strengths and weaknesses in Valley Crest's cost report, cost statement, information statement and payment request preparation

process relating to any and all costs submitted to Federal health care programs; and

iv. any recommendations the IRO may have to improve any of these systems, operations, and processes.

3. Compliance Engagement.

- a. Compliance Review. The IRO shall conduct a review of Valley Crest's compliance activities ("Compliance Review"). The Compliance Review shall consist of a review of Valley Crest's compliance with the obligations set forth in each Section of this Agreement, and a review of Valley Crest's compliance with certain provisions of the Settlement Agreement.
 - i. Agreement Obligations Review. The IRO shall evaluate Valley Crest's compliance with the obligations set forth in each Section of this Agreement.
 - ii. Unallowable Costs Review. The IRO shall determine whether Valley Crest has complied with its obligation not to charge to, or otherwise seek payment from, Federal or State payors for unallowable costs (as defined in the Settlement Agreement) and its obligation to identify to applicable Federal or State payors any unallowable costs included in payments previously sought from the United States, or any State Medicaid program. This unallowable cost analysis shall include, but not be limited to, payments sought in any cost reports, cost statements, information reports, or payment requests already submitted by Valley Crest or any of its subsidiaries, and to request, and agree, that such cost reports, cost statements, information reports or payment requests, even if already settled, be adjusted to account for the effect of the inclusion of the unallowable costs. In making this determination, the IRO may need to review cost reports and/or financial statements from the year of the Settlement Agreement, as well as from previous years.
- b. Compliance Review Report. The IRO shall prepare a report based upon the Compliance Review performed (the "Compliance Review Report"). The Compliance Review Report shall include:
 - i. the IRO's findings, supporting rationale, and a summary of such findings and rationale regarding Valley Crest's compliance with the terms of each Section of the Agreement, as applicable; and

- ii. the IRO's findings and supporting rationale regarding whether Valley Crest has complied with its obligation not to charge to, or otherwise seek payment from, Federal or State payors for unallowable costs (as defined in the Settlement Agreement) and its obligation to identify to applicable Federal or State payors any unallowable costs included in payments previously sought from such payor
- 4. <u>Validation Review</u>. In the event OIG has reason to believe that: (a) Valley Crest's Billing or Compliance Engagement fails to conform to the requirements of this Agreement or (b) the findings or Claims Review results are inaccurate, OIG may, at its sole discretion, conduct its own review to determine whether the Billing and Compliance Engagement comply with the requirements of the Agreement and/or the findings or Claims Review results are inaccurate. Valley Crest agrees to pay for the reasonable cost of any such review performed by OIG or any of its designated agents so long as it is initiated before one year after the final submission (as described in Section II) is received by OIG.

Prior to initiating a Validation Review, OIG shall notify Valley Crest of its intent to do so and provide an explanation for believing why such a review is necessary. In order to resolve any concerns raised by OIG, Valley Crest may request a meeting with OIG and OIG shall agree to meet with Valley Crest at a mutually agreeable time to discuss the results of any Engagement submissions or any Claims Review findings; present any additional or relevant information to clarify the results of the Engagements or to correct the inaccuracy of the Claims Review; and/or propose alternatives to the proposed Validation Review. Valley Crest agrees to provide any additional information as may be requested by OIG under this Section in an expedited manner. OIG will attempt in good faith to resolve any Billing or Compliance Engagement and/or Claims Review issues with Valley Crest prior to conducting a Validation Review. However, the final determination as to whether or not to proceed with a Validation Review shall be made at the sole discretion of OIG.

- 5. <u>Independence Certification</u>. The IRO shall include in its report(s) to Valley Crest a certification or sworn affidavit that it has evaluated its professional independence with regard to the Billing and Compliance Engagements and that it has concluded that it was, in fact, independent.
- E. <u>Confidential Disclosure Program.</u> Within ninety (90) days after the effective date of this Agreement, Valley Crest shall establish a Confidential Disclosure Program, which must include measures (e.g., a toll-free compliance telephone line) to enable employees, contractors, agents or other individuals to disclose, to the Compliance Officer or some other person who is not in the reporting individual's chain of command, any identified issues or questions associated with Valley Crest's policies, practices or procedures related to the Federal health care program that the individual believes to be inappropriate. Valley Crest shall publicize the existence of the hotline (e.g., e-mail to employees or post hotline number in prominent common areas).

The Confidential Disclosure Program shall emphasize a non-retribution, non-retaliation policy, and shall include a reporting mechanism for anonymous, confidential communication. Upon receipt of a complaint, the Compliance Officer (or designee) shall gather the information in such a way as to elicit all relevant information from the disclosing individual. The Compliance Officer (or designee) shall make a preliminary good faith inquiry into the allegations set forth in every disclosure to ensure that he or she has obtained all of the information necessary to determine whether a further review should be conducted. For any disclosure that is sufficiently specific so that it reasonably: (1) permits a determination of the appropriateness of the alleged improper practice, and (2) provides an opportunity for taking corrective action, Valley Crest shall conduct an internal review of the allegations set forth in such a disclosure and ensure that proper follow-up is conducted.

The Compliance Officer (or designee) shall maintain a confidential disclosure log, which shall include a record and summary of each allegation received, the status of the respective investigations, and any corrective action taken in response to the investigation. The confidential disclosure log shall be made available to OIG, upon request.

F. Ineligible Persons.

- 1. <u>Definition</u>. For the purposes of this Agreement, an "Ineligible Person" shall be any individual or entity who: (a) is currently excluded, debarred or otherwise ineligible to participate in the Federal health care programs or in Federal procurement or non-procurement programs; or (b) has been convicted of a criminal offense related to the provision of health care items or services, but has not yet been excluded, debarred or otherwise declared ineligible.
- 2. Screening Requirements. Valley Crest shall not hire as employees or engage as contractors any Ineligible Person. To prevent hiring or contracting with any Ineligible Person, Valley Crest shall screen all prospective employees and prospective contractors prior to engaging their services by (a) requiring applicants to disclose whether they are Ineligible Persons, and (b) reviewing the General Services Administration's List of Parties Excluded from Federal Programs (currently available through the Internet at http://epls.arnet.gov) and the HHS/OIG List of Excluded Individuals/Entities (currently available through the Internet at http://www.hhs.gov/oig) (these lists will hereinafter be referred to as the "Exclusion Lists").
- 3. Review and Removal Requirement. Within ninety (90) days of the effective date of this Agreement, Valley Crest will review its list of current employees and contractors against the Exclusion Lists. Thereafter, Valley Crest shall review its list of current employees and contractors at least annually. In addition, Valley Crest shall require employees and contractors to disclose immediately any debarment, exclusion or other event that makes the employee or contractor an Ineligible Person.

If Valley Crest has notice that an employee or contractor has become an Ineligible Person, Valley Crest will remove such person from responsibility for, or involvement with, Valley Crest's business operations related to the Federal health care programs and shall remove such person from any position for which the person's salary or the items or services rendered,

ordered, or prescribed by the person are paid in whole or part, directly or indirectly, by Federal health care programs or otherwise with Federal funds at least until such time as the person is reinstated into participation in the Federal health care programs.

- 4. Pending Charges and Proposed Exclusions. If Valley Crest has notice that an employee or contractor is charged with a criminal offense related to any Federal health care program, or is proposed for exclusion during his or her employment or contract, Valley Crest shall take all appropriate actions to ensure that the responsibilities of that employee or contractor have not and shall not adversely affect the quality of care rendered to any beneficiary, patient or resident, or the accuracy of any claims submitted to any Federal health care program.
- G. Notification of Government Investigation or Legal Proceedings. Within thirty (30) days of discovery, Valley Crest shall notify OIG, in writing, of any ongoing investigation or legal proceeding conducted or brought by a governmental entity or its agents involving an allegation that Valley Crest has committed a crime or has engaged in fraudulent activities. This notification shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding. Valley Crest shall also provide written notice to OIG within thirty (30) days of the resolution of the matter, and shall provide OIG with a description of the findings and/or results of the proceedings, if any.

H. Reporting.

1. Overpayments.

- a. Definition of Overpayments. For the purposes of this Agreement, an "overpayment" shall mean the amount of money Valley Crest has received in excess of the amount due and payable under any Federal health care program requirements. Valley Crest may not subtract any underpayments for purposes of determining the amount of relevant "overpayments."
- b. Reporting of Overpayments. If, at any time, Valley Crest identifies or learns of any overpayments, Valley Crest shall notify the payor (e.g., Medicare fiscal intermediary or carrier) and repay any identified overpayments within thirty (30) days of identification and take remedial steps within sixty (60) days of identification (or such additional time as may be agreed to by the payor) to correct the problem, including preventing the underlying problem and the overpayments from recurring. Notification and repayment to the contractor should be done in accordance with the contractor policies, and for Medicare contractors, must include the information contained on the Overpayment Refund Form, provided as Appendix B to this Agreement.

2. Material Deficiencies.

- a. Definition of Material Deficiency. For the purposes of this Agreement, a "Material Deficiency" means anything that involves:
 - (i) a substantial overpayment; or
 - (ii) a matter that a reasonable person would consider a potential violation of criminal, civil, or administrative laws applicable to any Federal health care program for which penalties or exclusion may be authorized.

A Material Deficiency may be the result of an isolated event or a series of occurrences.

- b. Reporting of Material Deficiencies. If Valley Crest determines that there is a Material Deficiency, Valley Crest shall notify OIG, in writing, within thirty (30) days of making the determination that the Material Deficiency exists. The report to OIG shall include the following information:
 - (i) If the Material Deficiency results in an overpayment, the report to OIG shall be made at the same time as the notification to the payor required in Section III.H.1, and shall include all of the information on the Overpayment Refund Form, as well as:
 - (A) the payor's name, address, and contact person to whom the overpayment was sent; and
 - (B) the date of the check and identification number (or electronic transaction number) on which the overpayment was repaid/refunded;
 - (ii) a complete description of the Material Deficiency, including the relevant facts, persons involved, and legal and Federal health care program authorities implicated;
 - (iii) a description of Valley Crest's actions taken to correct the Material Deficiency; and
 - (iv) any further steps Valley Crest plans to take to address the Material Deficiency and prevent it from recurring.

IV. <u>New Location and Business Units</u>

In the event that, after the effective date of this Agreement, Valley Crest changes locations or purchases or establishes new business units related to the furnishing of items or services that may be reimbursed by Federal health care programs, Valley Crest shall notify OIG of this fact as soon as possible, but no later than within thirty (30) days of the date of change of location, purchase or establishment. This notification shall include the location of the new operation(s), phone number, fax number, Medicare provider number(s) (if any), and the corresponding contractor's name and address that has issued each Medicare provider number. All Covered Persons at such locations shall be subject to the applicable requirements in this Agreement (e.g., completing certifications and undergoing training).

V. IMPLEMENTATION AND ANNUAL REPORTS

- A. <u>Implementation Report</u>. Within one hundred twenty (120) days after the effective date of this Agreement, Valley Crest shall submit a written report to OIG summarizing the status of its implementation of the requirements of this Agreement. This Implementation Report shall include:
 - 1. The name, address, phone number and position description of the Compliance Officer required by Section III.A;
 - 2. The names and positions of the members of the Compliance Committee required by Section III.A;
 - 3. A copy of Valley Crest's Code of Conduct required by Section III.B.1;
 - 4. A summary of the Policies and Procedures required by Section III.B.2;
 - 5. A description of the training programs required by Section III.C including a description of the targeted audiences and a schedule of when the training sessions were held;
 - 6. A certification by the Compliance Officer that:
 - a. The Policies and Procedures required by Section III.B have been developed, are being implemented, and have been distributed to all Covered Persons;
 - b. All Covered Persons have completed the Code of Conduct certification required by Section III.B.1; and
 - c. All Covered Persons have completed the training and executed the certification required by Section III.C.

- 7. A description of the Confidential Disclosure Program required by Section III.E;
- 8. The identity of the Independent Review Organization(s) and the proposed start and completion date of the first annual review;
- 9. A summary of personnel actions (other than hiring) taken pursuant to Section III.F;
- 10. A list of all of Valley Crest's locations and facilities owned or operated (including street and mailing addresses), the corresponding name under which each facility is doing business, the corresponding phone numbers and fax numbers, each facility's Federal health care program provider identification number(s), and the name, address, and telephone number of the payor (specific contractor) that issued each provider identification number; and
- 11. The certification required by Section V.C.
- B. <u>Annual Reports</u>. Valley Crest shall submit to OIG an Annual Report with respect to the status and findings of Valley Crest's compliance activities for each of the five (5) one-year periods beginning on the effective date of this Agreement. (The one-year period covered by each Annual Report shall be referred to as the "Reporting Period"). Each Annual Report shall include:
 - 1. Any change in the identity or position description of the Compliance Officer and/or members of the Compliance Committee described in Section III.A;
 - 2. A certification by the Compliance Officer that:
 - a. All Covered Persons have completed any Code of Conduct certifications required by Section III.B.1;
 - b. All Covered Persons have completed the training and executed the certification required by Section III.C; and
 - c. Valley Crest has complied with its obligations under the Settlement Agreement: (i) not to resubmit to any Federal health care program payors any previously denied claims related to the Covered Conduct addressed in the Settlement Agreement, and not to appeal any such denials of claims; and (ii) not to charge to or otherwise seek payment from Federal or state payors for unallowable costs (as defined in the Settlement Agreement); and (iii) to identify and adjust any past charges or claims for unallowable costs;

The documentation supporting this certification shall be available to OIG, upon request.

- 3. A summary of any significant changes or amendments to the Policies and Procedures required by Section III.B and the reasons for such changes (<u>e.g.</u>, change in contractor policy);
- 4. A description of the training required by Section III.C conducted during the Reporting Period, including a description of the targeted audiences, length of sessions, which sessions were mandatory and for whom, percentage of attendance, and a schedule of when the training sessions were held;
- 5. A complete copy of all report(s) prepared pursuant to the Independent Review Organization's Billing and Compliance Engagements, including a copy of the methodology used, along with a copy of the IRO's engagement letter(s);
- 6. Valley Crest's response and corrective action plan(s) to any issues raised by the Independent Review Organization(s);
- 7. A summary of Material Deficiencies (as defined in Section III.H) identified during the Reporting Period and the status of any corrective and preventative action relating to all such Material Deficiencies;
- 8. A report of the aggregate overpayments that have been returned to the Federal health care programs. Overpayment amounts should be broken down into the following categories: inpatient Medicare, outpatient Medicare, Medicaid (report each applicable state separately) and other Federal health care programs;
- 9. A summary of the disclosures in the confidential disclosure log required by Section III.E that: (a) relate to Federal health care programs; or (b) allege abuse or neglect of patients;
- 10. A description of any personnel action (other than hiring) taken by Valley Crest as a result of the obligations in Section III.F, and the name, title, and responsibilities of any person that falls within the ambit of Section III.F.4, and the actions taken in response to the obligations set forth in that Section;
- 11. A summary describing any ongoing investigation or legal proceeding reported pursuant to Section III.G. The summary shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding;
- 12. A description of all changes to the most recently provided list (as updated) of Valley Crest's locations (including locations and mailing addresses), the corresponding name under which each location is doing business, the

corresponding phone numbers and fax numbers, each location's Federal health care program provider identification number(s), and the name, address, and telephone number of the payor (specific contractor) that issued each provider identification number; and

13. The certification required by Section V.C.

The first Annual Report shall be received by the OIG no later than one hundred twenty (120) days after the end of the first Reporting Period. Subsequent Annual Reports shall be received by OIG no later than the anniversary date of the due date of the first Annual Report.

- C. <u>Certifications</u>. The Implementation Report and Annual Reports shall include a certification by the Compliance Officer that: (1) except as otherwise described in the applicable report, Valley Crest is in compliance with all of the requirements of this Agreement, to the best of his or her knowledge; and (2) the Compliance Officer has reviewed the Report(s) and has made reasonable inquiry regarding its content and believes that, upon such inquiry, the information is accurate and truthful.
- D. <u>Designation of Information</u>. Valley Crest shall clearly identify any portions of its submissions that it believes are trade secrets, or information that is commercial or financial and privileged or confidential, and therefore exempt from disclosure under the Freedom of Information Act ("FOIA"), 5 U.S.C. § 552. Valley Crest shall refrain from identifying any information as exempt from disclosure if that information does not meet the criteria for exemption from disclosure under FOIA.

VI. NOTIFICATIONS AND SUBMISSION OF REPORTS

Unless otherwise stated in writing subsequent to the effective date of this Agreement, all notifications and reports required under this Agreement shall be submitted to the entities listed below:

OIG:

Civil Recoveries Branch - Compliance Unit Office of Counsel to the Inspector General Office of Inspector General U.S. Department of Health and Human Services Cohen Building, Room 5527 330 Independence Avenue, SW Washington, DC 20201

Phone: 202-619-2078 Fax: 202-205-0604

Valley Crest:

John Bergold Compliance Officer Valley Crest Nursing Home 1551 East End Boulevard Wilkes-Barre, PA 18711 Phone: 570-826-1011

Fax: 570-825-1211

(with a copy to Counsel for Valley Crest):

Harriet Franklin, Esq. Stevens & Lee, PC 1275 Drummers Lane P.O. Box 236 Wayne, PA 19087 Phone: 610-293-5888

Fax: 610-293-4996

Unless otherwise specified, all notifications and reports required by this Agreement may be made by certified mail, overnight mail, hand delivery or other means, provided that there is proof that such notification was received. For the purposes of this requirement, internal facsimile confirmation sheets do not constitute proof of receipt.

VII. OIG INSPECTION, AUDIT AND REVIEW RIGHTS

In addition to any other rights OIG may have by statute, regulation, or contract, OIG or its duly authorized representative(s) may examine Valley Crest's books, records, and other documents and supporting materials and/or conduct an onsite review of Valley Crest's operations for the purpose of verifying and evaluating: (a) Valley Crest's compliance with the terms of this Agreement; and (b) Valley Crest's compliance with the requirements of the Federal health care programs in which it participates. The documentation described above shall be made available by Valley Crest to OIG or its duly authorized representative(s) at all reasonable times and upon reasonable notice for inspection, audit or reproduction. Furthermore, for purposes of this provision, OIG or its duly authorized representative(s) may interview any of Valley Crest's employees, contractors, or agents who consent to be interviewed at the individual's place of business during normal business hours or at such other place and time as may be mutually agreed upon between the individual and OIG. Valley Crest agrees to assist OIG in contacting and arranging interviews with such employees, contractors, and agents upon OIG's request. Valley Crest's employees may elect to be interviewed with or without a representative of Valley Crest present.

VIII. DOCUMENT AND RECORD RETENTION

Valley Crest shall maintain for inspection all documents and records relating to reimbursement from the Federal health care programs, or to compliance with this Agreement, for six (6) years (or longer if otherwise required by law).

IX. DISCLOSURES

Consistent with HHS's FOIA procedures, set forth in 45 C.F.R. Part 5, OIG shall make a reasonable effort to notify Valley Crest prior to any release by OIG of information submitted by Valley Crest pursuant to its obligations under this Agreement and identified upon submission by Valley Crest as trade secrets, or information that is commercial or financial and privileged and confidential, under the FOIA rules. With respect to such releases, Valley Crest shall have the rights set forth at 45 C.F.R. § 5.65(d). Valley Crest shall refrain from identifying any information as exempt from release if that information does not meet the criteria for exemption from disclosure under FOIA.

X. Breach and Default Provisions

Valley Crest is expected to fully and timely comply with all of the obligations herein throughout the term of this Agreement or other time frames herein agreed to.

- A. <u>Stipulated Penalties for Failure to Comply with Certain Obligations</u>. As a contractual remedy, Valley Crest and OIG hereby agree that failure to comply with certain obligations set forth in this Agreement may lead to the imposition of the following monetary penalties (hereinafter referred to as "Stipulated Penalties") in accordance with the following provisions.
- 1. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day, beginning ninety (90) days after the effective date of this Agreement and concluding at the end of the term of this Agreement, Valley Crest fails to have in place any of the following:
 - a. A Compliance Officer as described by Section III.A;
 - b. A Compliance Committee as described by Section III.A;
 - c. A Written Code of Conduct described by Section III.B;
 - d. Written Policies and Procedures as described by Section III.B;
 - e. A requirement that Covered Persons be trained as described in Section III.C; and
 - f. A Confidential Disclosure Program as described in Section III.E.

- 2. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Valley Crest fails meet any of the deadlines to submit any reports to OIG, or fails to retain an IRO as described in Section III.D.
- 3. A Stipulated Penalty of \$2,000 (which shall begin to accrue on the date the failure to comply began) for each day Valley Crest employs or contracts with an Ineligible Person and that person: (i) has responsibility for, or involvement with, Valley Crest's business operations related to the Federal health care programs; or (ii) is in a position for which the person's salary or the items or services rendered, ordered, or prescribed by the person are paid in whole or part, directly or indirectly, by Federal health care programs or otherwise with Federal funds (the Stipulated Penalty described in this paragraph shall not be demanded for any time period during which Valley Crest can demonstrate that it did not discover the person's exclusion or other ineligibility after making a reasonable inquiry (as described in Section III.F) as to the status of the person).
- 4. A Stipulated Penalty of \$1,500 (which shall begin to accrue on the date the Valley Crest fails to grant access) for each day Valley Crest fails to grant access to the information or documentation as required in Section V of this Agreement.
- 5. A Stipulated Penalty of \$1,000 (which shall begin to accrue ten (10) days after the date that OIG provides notice to Valley Crest of the failure to comply) for each day Valley Crest fails to comply fully and adequately with any obligation of this Agreement. In its notice to Valley Crest, OIG shall state the specific grounds for its determination that the Valley Crest has failed to comply fully and adequately with the Agreement obligation(s) at issue and steps Valley Crest must take to comply with the Agreement. A Stipulated Penalty as described in this paragraph shall not be demanded for any violation for which OIG has sought a Stipulated Penalty under paragraphs 1-4 of this Section.
- B. <u>Timely Written Requests for Extensions</u>. Valley Crest may, in advance of the due date, submit a timely written request for an extension of time to perform any act or file any notification or report required by this Agreement. Notwithstanding any other provision in this Section, if OIG grants the timely written request with respect to an act, notification, or report, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until one (1) day after Valley Crest fails to meet the revised deadline set by OIG. Notwithstanding any other provision in this Section, if OIG denies such a timely written request, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until two (2) business days after Valley Crest receives OIG's written denial of such request or the original due date, whichever is later. A "timely written request" is defined as a request in writing received by OIG at least five (5) business days prior to the date by which any act is due to be performed or any notification or report is due to be filed.

C. Payment of Stipulated Penalties.

1. <u>Demand Letter</u>. Upon a finding that Valley Crest has failed to comply with any of the obligations described in Section X.A and after determining that Stipulated Penalties

are appropriate, OIG shall notify Valley Crest of: (a) Valley Crest's failure to comply; and (b) OIG's exercise of its contractual right to demand payment of the Stipulated Penalties (this notification is hereinafter referred to as the "Demand Letter").

- 2. Response to Demand Letter. Within ten (10) days of the receipt of the Demand Letter, Valley Crest shall either: (a) cure the breach to OIG's satisfaction and pay the applicable Stipulated Penalties; or (b) request a hearing before an HHS administrative law judge ("ALJ") to dispute OIG's determination of noncompliance, pursuant to the agreed upon provisions set forth below in Section X.E. In the event Valley Crest elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until Valley Crest cures, to OIG's satisfaction, the alleged breach in dispute; however, the payment of such accrued Stipulated Penalties shall remain pending until the ALJ determination. Failure to respond to the Demand Letter in one of these two manners within the allowed time period shall be considered a material breach of this Agreement and shall be grounds for exclusion under Section X.D.
- 3. Form of Payment. Payment of the Stipulated Penalties shall be made by certified or cashier's check, payable to: "Secretary of the Department of Health and Human Services," and submitted to OIG at the address set forth in Section VI.
- 4. <u>Independence from Material Breach Determination</u>. Except as set forth in Section X.D.1.c, these provisions for payment of Stipulated Penalties shall not affect or otherwise set a standard for OIG's decision that Valley Crest has materially breached this Agreement, which decision shall be made at OIG's discretion and shall be governed by the provisions in Section X.D, below.

D. Exclusion for Material Breach of this Agreement

- 1. <u>Definition of Material Breach</u>. A material breach of this Agreement means:
 - a. a failure by Valley Crest to report a Material Deficiency, take corrective action and make the appropriate refunds, as required in Section III.H;
 - b. a repeated or flagrant violation of the obligations under this Agreement, including, but not limited to, the obligations addressed in Section X.A;
 - c. a failure to respond to a Demand Letter concerning the payment of Stipulated Penalties in accordance with Section X.C; or
 - d. a failure to retain and use an Independent Review Organization in accordance with Section III.D.
- 2. <u>Notice of Material Breach and Intent to Exclude</u>. The Parties agree that a material breach of this Agreement by Valley Crest constitutes an independent basis for Valley Crest's exclusion from participation in the Federal health care programs. Upon a determination by OIG that Valley Crest has materially breached this Agreement and that exclusion should be

imposed, OIG shall notify Valley Crest of: (a) Valley Crest's material breach; and (b) OIG's intent to exercise its contractual right to impose exclusion (this notification is hereinafter referred to as the "Notice of Material Breach and Intent to Exclude").

- 3. Opportunity to Cure. Valley Crest shall have thirty (30) days from the date of receipt of the Notice of Material Breach and Intent to Exclude to demonstrate to OIG's satisfaction that:
 - a. Valley Crest is in compliance with the obligations of the Agreement cited by OIG as being the basis for the material breach;
 - b. the alleged material breach has been cured; or
 - c. the alleged material breach cannot be cured within the 30-day period, but that: (i) Valley Crest has begun to take action to cure the material breach; (ii) Valley Crest is pursuing such action with due diligence; and (iii) Valley Crest has provided to OIG a reasonable timetable for curing the material breach.
- 4. Exclusion Letter. If at the conclusion of the thirty (30) day period, Valley Crest fails to satisfy the requirements of Section X.D.3, OIG may exclude Valley Crest from participation in the Federal health care programs. OIG will notify Valley Crest in writing of its determination to exclude Valley Crest (this letter shall be referred to hereinafter as the "Exclusion Letter"). Subject to the Dispute Resolution provisions in Section X.E, below, the exclusion shall go into effect thirty (30) days after the date of the Exclusion Letter. The exclusion shall have national effect and shall also apply to all other Federal procurement and non-procurement programs. Reinstatement to program participation is not automatic. If at the end of the period of exclusion, Valley Crest wishes to apply for reinstatement, Valley Crest must submit a written request for reinstatement in accordance with the provisions at 42 C.F.R. §§ 1001.3001-.3004.

E. <u>Dispute Resolution</u>

1. Review Rights. Upon OIG's delivery to Valley Crest of its Demand Letter or of its Exclusion Letter, and as an agreed-upon contractual remedy for the resolution of disputes arising under this Agreement, Valley Crest shall be afforded certain review rights comparable to the ones that are provided in 42 U.S.C. § 1320a-7(f) and 42 C.F.R. Part 1005 as if they applied to the Stipulated Penalties or exclusion sought pursuant to this Agreement. Specifically, OIG's determination to demand payment of Stipulated Penalties or to seek exclusion shall be subject to review by an ALJ and, in the event of an appeal, the Departmental Appeals Board ("DAB"), in a manner consistent with the provisions in 42 C.F.R. §§ 1005.2-1005.21. Notwithstanding the language in 42 C.F.R. § 1005.2(c), the request for a hearing involving Stipulated Penalties shall be made within ten (10) days of the receipt of the Demand Letter and the request for a hearing involving exclusion shall be made within twenty-five (25) days of receipt of the Exclusion Letter.

- 2. Stipulated Penalties Review. Notwithstanding any provision of Title 42 of the United States Code or Chapter 42 of the Code of Federal Regulations, the only issues in a proceeding for Stipulated Penalties under this Agreement shall be: (a) whether Valley Crest was in full and timely compliance with the obligations of this Agreement for which OIG demands payment; and (b) the period of noncompliance. Valley Crest shall have the burden of proving its full and timely compliance and the steps taken to cure the noncompliance, if any. If the ALJ agrees with OIG with regard to a finding of a breach of this Agreement and orders Valley Crest to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable twenty (20) days after the ALJ issues such a decision unless Valley Crest requests review of the ALJ decision by the DAB. If the ALJ decision is properly appealed to the DAB and the DAB upholds the determination of OIG, the Stipulated Penalties shall become due and payable twenty (20) days after the DAB issues its decision. Valley Crest will not be subject to accrued Stipulated Penalties should the ALJ or DAB rule for Valley Crest on appeal, except for any period of noncompliance by Valley Crest.
- 3. <u>Exclusion Review</u>. Notwithstanding any provision of Title 42 of the United States Code or Chapter 42 of the Code of Federal Regulations, the only issues in a proceeding for exclusion based on a material breach of this Agreement shall be:
 - a. whether Valley Crest was in material breach of this Agreement;
 - b. whether such breach was continuing on the date of the Exclusion Letter; and
 - c. whether the alleged material breach could not have been cured within the thirty (30) day period, but that:
 - (i) Valley Crest had begun to take action to cure the material breach within that period;
 - (ii) Valley Crest has pursued and is pursuing such action with due diligence; and
 - (iii) Valley Crest provided to OIG within that period a reasonable timetable for curing the material breach and Valley Crest has followed the timetable.

For the purposes of the exclusion herein, exclusion shall take effect only after an ALJ decision favorable to OIG, or, if the ALJ rules for Valley Crest, only after a DAB decision in favor of OIG. Valley Crest's election of its contractual right to appeal to the DAB shall not abrogate OIG's authority to exclude Valley Crest upon the issuance of an ALJ's decision in favor of OIG. If the ALJ sustains the determination of OIG and determines that exclusion is authorized, such exclusion shall take effect twenty (20) days after the ALJ issues such a decision, notwithstanding that Valley Crest may request review of the ALJ decision by the DAB. If the DAB finds in favor

of OIG after an ALJ decision adverse to OIG, the exclusion shall take effect twenty (20) days after the DAB decision.

XI. EFFECTIVE AND BINDING AGREEMENT

Consistent with the provisions in the Settlement Agreement pursuant to which this Agreement is entered, and into which this Agreement is incorporated, Valley Crest and OIG agree as follows:

- A. This Agreement shall be binding on the successors, assigns, and transferees of Valley Crest;
- B. This Agreement shall become final and binding on the date the final signature is obtained on the Agreement;
- C. Any modifications to this Agreement shall be made with the prior written consent of the Parties to this Agreement; and
- D. The undersigned Valley Crest signatories represent and warrant that they are authorized to execute this Agreement. The undersigned OIG signatory represents that he is signing this Agreement in his official capacity and that he is authorized to execute this Agreement.

ON BEHALF OF VALLEY CREST NURSING HOME

Thomas A. Makowski, Esc

Chairman

Luzerne County Commissioners

3/21/01 DATE

ON BEHALF OF THE OFFICE OF INSPECTOR GENERAL OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES:

Lewis Morris

Assistant Inspector General for Legal Affairs

Office of Inspector General

U. S. Department of Health and Human Services

APPENDIX A

A. Claims Review.

- 1. <u>Definitions</u>. For the purposes of the Claims Review, the following definitions shall be used:
 - a. <u>Claims Review Sample</u>: A statistically valid, randomly selected, sample of items selected for appraisal in the Claims Review.
 - b. <u>Item</u>: Any discrete unit that can be sampled (<u>e.g.</u>, code, line item, beneficiary, patient encounter, etc.). For the review of Medicare claims, the Item will be the claim (UB-92) and each associated MDS.
 - c. Overpayment: Consistent with the definition of Overpayment as articulated in section III.H.1.a of the Agreement, the amount of money Valley Crest has received in excess of the amount due and payable under any Federal health care program requirements. For the purposes of the Claims Review and all reporting to OIG under this Agreement, Valley Crest shall not subtract or "net out" underpayments when determining the amount of relevant Overpayments.
 - d. <u>Paid Claim</u>: A code or line item submitted by Valley Crest and for which Valley Crest has received reimbursement from the Medicare and Medicaid programs.
 - e. <u>Population</u>: All Items for which Valley Crest has submitted a code or line item and for which Valley Crest has received reimbursement from the Medicare and Medicaid programs (<u>i.e.</u>, a Paid Claim) during the 12-month period covered by the Claims Review. To be included in the Population, an Item must have resulted in at least one (1) Paid Claim.
 - f. <u>Probe Sample</u>: A sample of Items selected through simple random sampling from the Population for the purpose of estimating the mean and standard deviation of the Population. The estimated mean and standard deviation of the Population are to be used to calculate the minimum number of Items to be included in the Claims Review Sample.
 - g. <u>RAT-STATS</u>: OIG's Office of Audit Services Statistical Sampling Software. RAT-STATS is publicly available to download through the Internet at "www.hhs.gov/oig/oas/ratstat.html".
- 2. <u>Description of Claims Review</u>. The Claims Review shall consist of an appraisal of a statistically valid sample of Items (the Claims Review Sample) that can be projected to the total Population.
 - a. Confidence and Precision Requirements. The Claims Review Sample must

contain a sufficient number of Items so that if the Overpayments identified in the Claims Review Sample were projected to the Population, the projection would provide a 90% confidence level and a maximum relative precision (i.e., semiwidth of the confidence interval) of plus or minus 25% of the point estimate. In other words, if the Claims Review Overpayment results were projected to the Population at a 90% confidence level, the confidence interval (expressed in dollars) must be sufficiently narrow that the upper bound of the confidence interval would not exceed 125% of the midpoint of the confidence interval (the point estimate), and the lower bound of the confidence interval would not be less than 75% of the midpoint of the confidence interval.

- b. <u>Use of a Probe Sample to Determine Claims Review Sample Size</u>. To determine how many Items must be included in the Claims Review Sample to meet the 90% confidence level and 25% precision requirements, the mean and the standard deviation of the Population must be estimated. These estimates shall be developed through the use of a single Probe Sample. The Probe Sample shall be used to determine the minimum Claims Review Sample size through one of the two following options:
 - i. Probe Sample with a Minimum Size of Thirty (30) Items. The Probe Sample shall include at least thirty (30) Items, and shall be selected through the use of RAT-STATS' "Random Numbers" function. Once all Paid Claims associated with the Items included in the Probe Sample have been reviewed, the estimated mean and standard deviation of the Population shall be determined. This determination is based on the Overpayment amount received by Valley Crest for each Item in the sample. The "Variable Appraisals" function of RAT-STATS shall be used to calculate the estimated mean and standard deviation of the Population. For the purposes of estimating the mean and standard deviation of the Population, and entering this information into the "Variable Appraisals" function of RAT-STATS, any underpayment identified for a Paid Claim in the Probe Sample shall be treated as a zero overpayment. If no Overpayments are found in this Probe Sample, then a second Probe Sample, of at least thirty (30) Items, must be selected and reviewed. The estimated mean and standard deviation of the Population (based on the amount of Overpayments received by Valley Crest for each sample Item) shall be determined from this Probe Sample, using RAT-STATS' "Variable Appraisals" function. If no Overpayments are found in this second Probe Sample, then the Claims Review can be terminated with the results of the second Probe Sample, and the results of the two Probe Samples shall be reported in lieu of the Claims Review when preparing and submitting the Claims Review Report (see section B, below); or
 - ii. <u>Probe Sample with a Minimum Size of Fifty (50) Items</u>. The Probe Sample shall include at least fifty (50) Items, and shall be selected through

the use of RAT-STATS' "Random Numbers" function. Once all Paid Claims associated with the Items included in the Probe Sample have been reviewed, the estimated mean and standard deviation of the Population shall be determined. This determination is based on the Overpayment amount received by Valley Crest for each Item in the sample. The "Variable Appraisals" function of RAT-STATS shall be used to calculate the estimated mean and standard deviation of the Population. For the purposes of estimating the mean and standard deviation of the Population, and entering this information into the "Variable Appraisals" function of RAT-STATS, any underpayment identified for a Paid Claim in the Probe Sample shall be treated as a zero overpayment. If no Overpayments are found in this fifty (50) Item Probe Sample, then the Claims Review can be terminated with the review of the Probe Sample and the results of the Probe Sample shall be reported in lieu of the results of the Claims Review when preparing and submitting the Claims Review Report (see section B. below).

- c. Calculation of Claims Review Sample Size and Selection of the Claims Review Sample. The estimates of the mean and the standard deviation of the Population obtained through the review of the Probe Sample shall be used to calculate the minimum size of the Claims Review Sample. In order to determine the minimum number of Items that must be included in the Claims Review Sample to meet the 90% confidence level and 25% precision requirements, RAT-STATS' "Sample Size Estimators" (located under the "Utility Programs" file) shall be used. The Claims Review Sample shall be selected by using RAT-STATS' "Random Numbers" function, and shall be selected from the entire Population, with the Population including those Items reviewed as part of the Probe Sample, so that all Items in the Population have an equal chance of inclusion in the Claims Review Sample.
- d. <u>Item Appraisal</u>. For each Item appraised (either as part of the Claims Review Sample or of the Probe Sample), only Paid Claims shall be evaluated. Every Paid Claim in the Claims Review Sample shall be evaluated by the IRO to determine whether the claim submitted was correctly coded, submitted, and reimbursed. Each appraisal must be sufficient to provide all information required under the Claims Review Report.
- e. <u>Paid Claims without Supporting Documentation</u>. For the purpose of appraising Items included in the Claims Review and/or the Probe Sample, any Paid Claim for which Valley Crest cannot produce documentation sufficient to support the Paid Claim shall be considered an error and the total reimbursement received by Valley Crest for such Paid Claim shall be deemed an Overpayment. Replacement sampling for Paid Claims with missing documentation is not permitted.

- f. <u>Use of First Samples Drawn</u>. For the purposes of all samples (Probe Sample(s) and Claims Review Sample(s)) discussed in this Appendix, the Paid Claims associated with the Items selected in the first sample (or first sample for each strata, if applicable) shall be used. In other words, it is not permissible to generate a number of random samples and then select one for use as the Probe Sample or Claims Review Sample.
- B. <u>Claims Review Report</u>. The following information shall be included in each Claims Review Report:
 - 1. Claims Review Methodology.
 - a. <u>Claims Review Objective</u>: A clear statement of the objective intended to be achieved by the Claims Review.
 - b. <u>Sampling Unit</u>: A description of the Item as that term is utilized for the Claims Review. As noted in Section A.1.b above, for the purposes of this Billing Engagement, the term "Item" may refer to any discrete unit that can be sampled (e.g., claim, line item, beneficiary, patient encounter, etc.).
 - c. <u>Claims Review Population</u>: A description of the Population subject to the Claims Review.
 - d. <u>Sampling Frame</u>: A description of the sampling frame, which is the totality of Items from which the Probe and Claims Review Sample have been selected and an explanation of the methodology used to identify the sampling frame. In most circumstances, the sampling frame will be identical to the Population.
 - e. <u>Sources of Data</u>: A description of the documentation relied upon by the IRO when performing the Claims Review (<u>e.g.</u>, medical records, physician orders, certificates of medical necessity, requisition forms, local medical review policies, HCFA program memoranda, Medicare carrier or intermediary manual or bulletins, other policies, regulations, or directives).
 - f. <u>Review Protocol</u>: A narrative description of how the Claims Review was conducted and what was evaluated.

2. Statistical Sampling Documentation.

- a. The number of Items appraised in the Probe Sample(s) and in the Claims Review Sample.
- b. A copy of the RAT-STATS printout of the random numbers generated by the "Random Numbers" function.

- c. A copy of the RAT-STATS printout of the "Sample Size Estimators" results used to calculate the minimum number of Items for inclusion in the Claims Review Sample.
- d. A copy of the RAT-STATS printout of the "Variable Appraisals" function results for the Probe Sample.
- e. The Sampling Frame used in the Probe Sample(s) and the Claims Review Sample will be available to the OIG upon request.

3. Claims Review Results.

- a. Total number and percentage of instances in which the IRO determined that the Paid Claim submitted by Valley Crest ("Claim Submitted") differed from what should have been the correct claim ("Correct Claim"), regardless of the effect on the payment.
- b. Total number and percentage of instances in which the Claim Submitted differed from the Correct Claim and in which such difference resulted in an Overpayment to Valley Crest.
- c. The total dollar amount of all Paid Claims in the Claims Review Sample and the total dollar amount of Overpayments associated with the Paid Claims identified by the Claims Review. (This is the total dollar amount of the Overpayments identified in Section B.3.b above.) The IRO may, in its report to Valley Crest, identify underpayments, but any underpayments identified during the Claims Review shall not be offset or "netted out" of the total dollar amount of Paid Claims or of the Overpayments when reporting these amounts in the Claims Review Report to OIG.
- d. A spreadsheet of the Claims Review results that includes the following information for each Paid Claim appraised: Federal health care program billed, beneficiary health insurance claim number, date of service, procedure code submitted, procedure code reimbursed, allowed amount reimbursed by payor, correct procedure code (as determined by the IRO), correct allowed amount (as determined by the IRO), dollar difference between allowed amount reimbursed by payor and the correct allowed amount. (See Attachment 1 to this Appendix.)
- 4. <u>Credentials</u>. The names and credentials of the individuals who: (1) designed the statistical sampling procedures and the review methodology utilized for the Claims Review; and (2) performed the Claims Review.

OVERPAYMENT REFUND

TO B	E COMPLETED BY MEDICARE CONTRACTOR
Date:	
Contractor Deposit Control	# Date of Deposit:
Contractor Contact Name:	Phone #
Contractor Address.	· -
Contractor Fax:	
TO BE	COMPLETED BY PROVIDER/PHYSICIAN/SUPPLIER
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information, should accompo	iny every voluntary refund so that receipt of check is properly recorded and applied
*	
	UPPLIERNAME
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CONTACT PERSON:	OTTLIER #CHECK NUMBER#
AMOUNT OF CHECK \$	PHONE #CHECK DATE
	CHECK DATE
	REFUND INFORMATION
For each Claim, provide th	e following:
Medicare Claim Number	HIC # Claim Amount Refunded \$ Istment: (Select reason code from list below. Use one reaso)
Reason Code for Claim Adju	stment: (Select reason code from list below. Use one reason
n per cianni)	
(Please list	all claim numbers involved. Attach separate sheet, if necessary)
Note: It Specific Pattent/H	(C/Claim #/Claim Amount data not available for all claims due to Chairtine
sampung, pieuse ini	dicate methodology and formula used to determine amount and reason for
overpaymen.	
For Institutional Facilities (Only:
Cost Report Year(s)	
In multiple cost report years a	are involved, provide a breakdown by amount and corresponding cost report year.)
Tulpan gilli todan ett ettille	ements:
	egrity Agreement with OIG? Yes No
Reason Codes: Billing/Clerical Error	Manior
11 - Corrected Date of Service	MSP/Other Payer Involvement Miscellaneous
2 - Duplicate	08 - MSP Group Health Plan Insurance 13 - Insufficient Documentation
3 - Corrected CPT Code 4 - Not Our Patient(s)	09 - MSP No Fault Insurance 10 - MSP Liability Insurance 11 - MSP, Workers Comp. (Including 12 - Mstrictelit Documentation 13 - Insurficient Documentation 14 - Patient Enrolled in an HMO 15 - Services Not Rendered 16 - Medical Necessity 17 Other (Please Service)
4 - Not Our Patient(s)	11 - MSP, Workers Comp. (Including 16 - Medical Necessity
5 - Modifier Added/Removed	Didek Lung 17 - Onler (Please Specify)
6 - Billed in Error 7 - Corrected CPT Code	12 - Veterans Administration
7 - Corrected CPT Code	